Research

Age related, structured educational programmes for the management of atopic dermatitis in children and adolescents: multicentre, randomised controlled trial

Doris Staab, Thomas L Diepgen, Manigé Fartasch, Jörg Kupfer, Thomas Lob-Corzilius, Johannes Ring, Sibylle Scheewe, Reginald Scheidt, Gerhard Schmid-Ott, Christina Schnopp, Rüdiger Szczepanski, Thomas Werfel, Marita Wittenmeier, Ulrich Wahn, Uwe Gieler

Abstract

Objective To determine the effects of age related, structured educational programmes on the management of moderate to severe atopic dermatitis in childhood and adolescence.
Design Multicentre, randomised controlled trial.
Setting Seven hospitals in Germany.
Participants Parents of children with atopic dermatitis aged 3 months to 7 years (n = 274) and 8-12 years (n = 102), adolescents with atopic dermatitis aged 13-18 years (n = 70), and controls (n = 244, n = 83, and n = 50, respectively).
Interventions Group sessions of standardised intervention programmes for atopic dermatitis once weekly for six weeks or no education (control group).
Main outcome measures Severity of eczema (scoring of atopic dermatitis scale), subjective severity (standardised questionnaires), and quality of life for parents of affected children aged less than 13 years, over 12 months.
Results Significant improvements in severity of eczema and subjective severity were seen in all intervention groups compared with control groups (total score for severity: age 3 months to 7 years −17.5, 95% confidence intervals −19.6 to −15.3 *v* −12.2, −14.3 to −10.1; age 8-12 years −16.0, −20.0 to −12.0 *v* −7.8, −11.4; −4.3; and age 13-18 years −19.7, −23.7 to −15.7 *v* −5.2, −10.5 to 0.1). Parents of affected children aged less than 7 years experienced significantly better improvement in all five quality of life subscales, whereas parents of affected children aged 8-12 years experienced significantly better improvement in three of five quality of life subscales.
Conclusion Age related educational programmes for the control of atopic dermatitis in children and adolescents are effective in the long term management of the disease.

Introduction

Atopic dermatitis is a chronically relapsing, inflammatory skin disease affecting up to a fifth of schoolchildren.[1] Recent studies suggest that this prevalence is increasing in industrialised countries.[2] Atopic dermatitis commonly begins in infancy or early childhood, and the symptoms of itching, scratching, and sleeplessness can place a burden on the whole family.[3] Lack of information, overstrain, helplessness, and lack of confidence in medical treatment lead to suboptimal management of the disease and increasing use of healthcare resources, including alternative therapies.

Educational programmes aim to empower patients and carers in solving the problems arising from chronic diseases,[4] and meta-analysis of results has highlighted the need for standardised methods so that improvements in self management of chronic disease can be more accurately assessed.[5 6] Although several educational interventions have been developed for adults with atopic dermatitis, the literature on educational programmes for children and their parents is sparse.[7] In addition, studies have not used the type of standardised, structured intervention that is proving highly beneficial in the management of other chronic atopic conditions in children, such as asthma.[8]

Our study, the German atopic dermatitis intervention study, was set up to develop standardised interventions for the self management of atopic dermatitis and to assess their effects. We have used our collective experience and the input from three consensus conferences to define the content and structure of such a programme, including study design and choice of evaluation instruments. Here we report data, stratified into three age groups, collected from 992 families with children aged 3 months to 18 years with atopic dermatitis, within a multicentre, randomised controlled study. We determined the long term effect of age related, structured educational programmes on the control of moderate to severe atopic dermatitis in childhood and adolescence by assessing changes in disease severity, itch, and parents' quality of life over 12 months.

Participants and methods

The three participating groups were parents of children with atopic dermatitis aged 3 months to 7 years and 8-12 years and adolescents with atopic dermatitis aged 13-18 years (table 1). Participants were recruited from seven centres in Germany: three children's hospitals (Berlin, Osnabrück, and Cologne), three hospitals specialising in dermatology (Munich, Erlangen, and Hannover), and one department of psychosomatic medicine (Giessen). Atopic dermatitis was diagnosed by dermatologists or paediatricians. The inclusion criteria were diagnosis of atopic dermatitis according to the criteria of Hanifin and Rajka,[9] eczema duration a minimum of at least three months, and a severity of eczema of at least 20 points according to the scoring of atopic dermatitis scale.[10] Exclusion criteria were other acute or

Study centres and members are on bmj.com

Table 1 Structure and content of educational programme aimed at parents of children with atopic dermatitis and adolescents with atopic dermatitis

Session	Trainer	Target groups			Topics
		3 months to 7 years	8-12 years	13-18 years	
1	Paediatrician or dermatologist and psychologist	Parents	Parents and children*	Adolescents (parents optional)	Introduction round, basic medical information about atopic dermatitis, introduction of relaxation technique
2	Psychologist	Parents	Parents and children	Adolescents (parents optional)	Stress management, dealing with itching and scratching and sleep disturbances
3	Nurse	Parents	Parents and children	Adolescents	Recognition and avoidance of trigger factors, daily skin care
4	Paediatrician or dermatologist	Parents	Parents and children	Adolescents	Stage related treatment of symptoms, unconventional therapies
5	Dietician	Parents	Parents and children	Adolescents	General child nutrition, food allergies in atopic dermatitis, different forms of diets
6	Paediatrician or dermatologist and psychologist	Parents	Parents and children	Adolescents	Issues of coping; self management plan, problems in transfer to daily routine

*Courses for parents and children were held in parallel in two rooms; children were educated by same instructor throughout (trained nurse or tutor).

chronic illnesses or psychiatric disorders requiring treatment. A total of 992 patients were eligible and agreed to participate in the study. All participants (parents and adolescents) gave written informed consent.

After one year, 823 participants could be reached for evaluation: dropout rate of 17% (10% in the intervention group, 24% in the control group).

Study design

The study was designed as a randomised, controlled intervention study. Randomisation was carried out anonymously by an independent study centre in Heidelberg using computer generated random numbers. The randomisation code was concealed in closed envelopes from those entering patients into the study. The treatment programme consisted of six, weekly group sessions (5-8 participants), lasting two hours each. Patients were drawn consecutively from the seven study centres. The patients and their parents in the intervention and control groups were followed up at six (data not shown) and 12 months. The sample size estimation and power calculation was based on the severity of eczema (total on scoring of atopic dermatitis scale) as the primary outcome. With an effect size d of 0.40,[11] $\alpha = 5\%$, and $\beta = 20\%$, we calculated that we would need 125 participants in each group, assuming a 20% loss during follow-up. No interims analysis was carried out, no stopping rules.

The participants could not be blinded as they were aware that they were receiving education, and it was also not possible for the trainers to be blinded. The scoring of atopic dermatitis scale was measured by investigators who were not actively involved as trainers.

Interventions

The educational programme was standardised to provide theme centred group training and comprised six, once weekly sessions, lasting two hours each. Parents of affected children aged 3 months to 7 years received education, with the contents of the sessions based on previously reported work.[12] The parents of affected children aged 8-12 years attended separate educational sessions. Adolescents aged 13-18 years attended educational sessions tailored to their needs.[13] These sessions covered medical, nutritional, and psychological issues, and were carried out by a multiprofessional team of dermatologists or paediatricians, psychologists, and dietitians, who had undergone a 40 hour training programme to qualify as trainers (see table 1). The contents and structure of the programme and didactic methods were discussed and worked out by an interdisciplinary consensus group over two years before starting the programme.

A manual specified the content of each session, and participants were given handouts summarising the timetable and the most important points of the sessions. The sessions also encouraged participants to share personal experiences and to try out newly learned skills.

The educational programme did not contain a therapy mandate, and any topical or systemic individual therapy (for example, prescriptions or specific diets) remained the responsibility of the patients' doctors.

Outcome measures

The primary end points were the differences in severity of eczema and parents' quality of life between the start of the study (baseline) and follow-up at 12 months.

Severity of eczema

We graded the severity of eczema using the scoring of atopic dermatitis scale.[10] This scale is based on the extent of eczema, the morphology of the lesions, and the two subjective items of sleep disturbance during the night and itch. The objective scoring of atopic dermatitis is the total score on the scoring of atopic dermatitis scale minus the scores related to both subjective items.

Subjective severity score

The subjective severity of eczema was measured using the "skin detective,"[14] a subjective score for severity related to part of the scoring of atopic dermatitis scale. The parents compared the morphology of their child's skin lesions with those of illustrations evaluated by experts.[14]

Itch questionnaires

We used two standardised questionnaires to measure itching behaviour: JUCKKI, which contains 15 items and is aimed at 8-12 year olds, and JUCKJU, which comprises 18 items and is aimed at 13-18 year olds.[15] The final versions of these two questionnaires were tested after preliminary studies in a group of 204 children and 168 adolescents. Two-factorial scale solutions resulted for both questionnaires. The two factors covered the areas catastrophisation (negative thoughts on pain that have got out of control) and coping. The internal consistence can be rated satisfactory to good, with values between 0.72 and 0.91. The questionnaires on itching cognitions provide two age appropriate procedures for children and adolescents with which differential aspects of these constructs can be reliably measured.[15]

Quality of life for parents of children aged less than 13 years

Parents' quality of life was measured with the German questionnaire "Quality of life in parents of children with atopic dermatitis." This questionnaire was developed as part of the Berlin public health study "Evaluation of an educational programme for parents of children with atopic dermatitis," and has been validated[16]; it consists of 26 items, which can be divided by factor

analysis into five interpretable subscales: psychosomatic well-being, effects on social life, confidence in medical treatment, emotional coping, and acceptance of the disease. Convergent validity of this instrument has been tested. The questionnaire also highlights differences between parents of children with varying degrees of disease severity, which is a prime indicator of clinical relevance. The questionnaire has shown high intraclass coefficients for test retest reliability. The reliability for the subscales was medium to high, which was expressed by a Cronbach's α of between 0.57 and 0.90. The intercorrelations of the dimensions are moderate (0.20-0.63), which shows that each dimension gives independent information on the respective aspects of quality of life.

Statistical analysis

All statistical analyses were carried out using SAS. For statistical tests we used non-parametric methods. We used analyses of covariance to compare values at baseline with those at 12 months between the study arms.

Results

In total, 1010 patients were assessed for eligibility to take part in the study: 645 parents of children with atopic dermatitis aged 3 months to 7 years, 214 parents of affected children aged 8-12 years, and 151 adolescents aged 13-18 years. Of these, 992 participants were randomised (figure). In all age groups the severity of eczema did not differ significantly between the intervention and control groups at baseline (table 2). Additionally, no statistically significant differences were found between the intervention and control participants for all other outcome measures at baseline. After losses during follow-up, the number of participants in the intervention arms was 274 for children aged 3 months to 7 years; 102 for children aged 8-12 years; and 70 for adolescents aged 13-18 years. Comparable numbers in the control groups were 244, 83, and 50. The clinical characteristics and results of all outcome measures at baseline did not differ significantly between participants lost to follow-up and those remaining.

Severity of eczema according to scoring of atopic dermatitis scale

At baseline the mean score for severity of eczema was greater than 40 points in the intervention and control groups. At 12 months' follow-up the severity of eczema had decreased in all groups, but the decrease was significantly greater in the intervention arms (table 3).

Table 2 Baseline characteristics of groups receiving educational intervention for atopic dermatitis or no education (control)

Variable	Intervention groups	Control groups
3 months to 7 years:	n=274	n=244
Mean (SD) age (years)	2.4 (1.8)	2.4 (1.9)
No (%) male	143 (52)	127 (52)
8-12 years:	n=102	n=83
Mean (SD) age (years)	9.5 (1.6)	9.5 (1.5)
No (%) male	41 (40)	40 (48)
13-18 years:	n=70	n=50
Mean (SD) age (years)	14.9 (1.7)	14.8 (1.7)
No (%) male	29 (41)	18 (36)

Subjective severity score

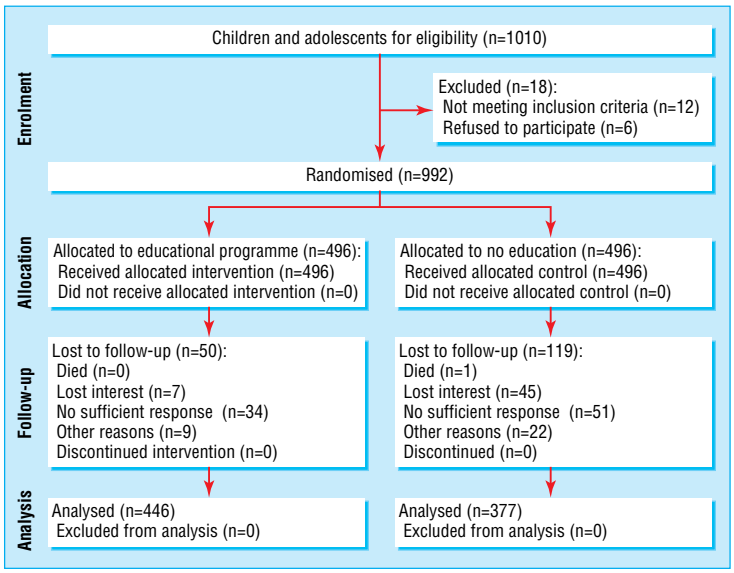
Self evaluation of atopic dermatitis by children and adolescents has been shown to be similar to evaluation by experts. In our study the subjective severity score for eczema decreased significantly more in the intervention groups (table 3).

Itching behaviour in 8-12 year olds and 13-18 year olds

Table 3 shows the results of the subscales of the itch questionnaires in children aged 8-12 years and the adolescents at baseline and 12 months' follow-up. In the 8-12 year olds, significantly greater improvements were shown in the intervention group for the subscales catastrophisation (intervention group, −7.0, 95% confidence interval −8.9 to −5.1; control group, −1.8, −3.5 to −0.2: $P<0.0001$) and coping (1.0, −0.3 to 2.3 *v* −0.4, −1.6 to 0.8: $P<0.05$). In adolescents only the subscale catastrophisation showed a significantly greater improvement (table 3).

Quality of life for parents of children aged less than 13 years

Improvement in quality of life for parents of children aged 3 months to 7 years was significantly greater in the intervention group for all five subscales of the quality of life questionnaire (table 4). Improvement in quality of life for parents of children aged 8-12 years was significantly greater in the intervention group for three of the five subscales. The improvement in the subscales for confidence in medical treatment, emotional coping,



Flow of participants through trial

Table 3 Outcome variables using analysis of covariance at baseline and 12 months' follow-up for groups receiving an educational programme in atopic dermatitis or no education

	Intervention			No intervention			No intervention minus intervention	
Outcome by age group	Baseline	12 months	Mean (95% CI) difference	Baseline	12 months	Mean (95% CI) difference	Difference (95% CI)	P value
3 months to 7 years:		n=274			n=244			
Total severity score*	41.1 (16.6)	23.7 (16.7)	–17.5 (–19.6 to –15.3)	40.6 (15.2)	28.4 (16.5)	–12.2 (–14.3 to –10.1)	–5.2 (–8.2 to –2.2)	0.0002
Objective severity score*	32.5 (14.3)	19.5 (13.9)	–13.0 (–14.8 to –11.2)	31.4 (13.0)	22.6 (13.4)	–8.7 (–10.5 to –7.0)	–4.2 (–6.8 to –1.7)	0.0009
Subjective severity	8.3 (3.8)	4.8 (3.4)	–3.3 (–3.9 to –2.8)	8.3 (3.8)	6.1 (3.6)	–2.2 (–2.7 to –1.6)	–1.1 (–1.9 to –0.3)	<0.001
8-12 years:		n=102			n=83			
Total severity score*	41.8 (16.6)	25.8 (17.7)	–16.0 (–20.0 to –12.0)	40.4 (15.1)	32.6 (16.5)	–7.8 (–11.4 to –4.3)	–8.2 (–13.6 to –2.8)	0.003
Objective severity score*	34.0 (14.1)	21.7 (15.1)	–12.3 (–15.6 to –8.9)	32.5 (13.1)	26.9 (14.2)	–5.6 (–8.7 to –2.5)	–6.7 (–11.2 to –2.1)	0.005
Subjective severity	8.5 (3.9)	4.9 (2.9)	–3.7 (–4.6 to –2.7)	8.6 (3.5)	7.0 (3.8)	–1.6 (–2.5 to –0.7)	–2.1 (–3.4 to –0.8)	<0.001
Itching behaviour								
Catastrophisation†	13.6 (8.5)	6.6 (6.5)	–7.0 (–8.9 to –5.1)	13.6 (8.2)	11.8 (8.6)	–1.8 (–3.5 to –0.2)	–5.2 (–7.7 to –2.7)	<0.0001
Coping	7.7 (5.1)	8.8 (5.4)	1.0 (–0.3 to 2.3)	7.6 (4.6)	7.2 (5.0)	–0.4 (–1.6 to 0.8)	1.5 (–0.3 to +3.2)	0.047
13-18 years:		n=70			n=50			
Total severity score*	43.1 (14.7)	23.4 (12.6)	–19.7 (–23.7 to –15.7)	40.4 (13.9)	35.2 (15.2)	–5.2 (–10.5 to 0.1)	–14.5 (–21.2 to –7.9)	<0.0001
Objective severity score*	34.4 (12.4)	19.5 (11.1)	–15.0 (–18.4 to –11.6)	33.4 (12.0)	28.3 (12.0)	–5.1 (–9.5 to –0.6)	–9.9 (–15.5 to –4.3)	<0.0001
Subjective severity	8.9 (3.2)	5.8 (3.4)	–3.1 (–4.1 to –2.2)	8.8 (3.5)	8.1 (4.0)	–1.0 (–2.1 to 0.1)	–2.1 (–3.5 to –0.7)	<0.0022
Itching behaviour								
Catastrophisation†	16.6 (7.9)	9.8 (8.1)	–6.8 (–8.6 to –5.0)	16.9 (8.6)	14.9 (9.0)	–2.0 (–3.9 to –0.2)	–4.7 (–7.3 to –2.2)	0.0002
Coping	15.4 (7.8)	15.2 (8.2)	–0.2 (–1.9 to 1.5)	14.0 (7.0)	14.5 (7.0)	0.4 (–1.2 to 2.1)	–0.6 (–3.0 to +1.7)	0.875

*Scoring of atopic dermatitis scale.
†Negative thoughts on pain that have got out of control.

and acceptance of the disease were significantly greater in the intervention group (table 4). The subscales for psychosomatic wellbeing and effects on social life did not differ significantly between the intervention and control groups (table 4).

Discussion

Age related educational programmes for the control of atopic dermatitis in children and adolescents are significantly more effective in the long term management of the disease than is conventional treatment. Over a 12 month period statistically significant benefits were seen in the intervention groups for severity of eczema, subjective severity, and effect on parents' quality of life. One important feature of our study was the inclusion of a control group, since improvements in outcomes are also observed in the absence of parental or patient education. The educational intervention is probably complex as it can have a range of specific and non-specific effects and interactions between such effects. The benefit may not be attributable solely to the educational interventions in the absence of a controlled group that has simple non-directive group work with no educational programme. We assumed that patients in the control

Table 4 Results using analysis of covariance of parental quality of life questionnaire at baseline and 12 months for groups receiving an educational programme in atopic dermatitis or no education

	Intervention			No intervention			No intervention minus intervention	
Outcome by age group	Baseline	12 months	Mean (95% CI) difference	Baseline	12 months	Mean (95% CI) difference	Difference (95% CI)	P value
3 months to 7 years:		n=274			n=244			
Psychosomatic wellbeing	29.3 (7.6)	33.7 (7.0)	4.4 (3.6 to 5.2)	29.1 (7.7)	32.1 (7.1)	3.1 (2.2 to 3.9)	1.4 (0.2 to 2.5)	0.0040
Effects on social life	24.9 (4.0)	26.7 (3.4)	1.8 (1.4 to 2.3)	24.5 (4.4)	25.5 (4.1)	1.0 (0.6 to 1.5)	0.8 (0.2 to 1.4)	<0.0001
Confidence in medical treatment	16.0 (4.0)	20.0 (3.5)	4.0 (3.5 to 4.5)	15.8 (4.4)	17.8 (4.2)	1.9 (1.4 to 2.4)	2.1 (1.4 to 2.8)	<0.0001
Emotional coping	13.7 (3.2)	16.8 (2.9)	3.1 (2.7 to 3.5)	14.2 (3.4)	15.4 (3.2)	1.1 (0.7 to 1.6)	1.9 (1.3 to 2.5)	<0.0001
Acceptance of disease	7.1 (1.9)	8.2 (1.7)	1.1 (0.8 to 1.3)	7.0 (1.9)	7.5 (1.8)	0.5 (0.3 to 0.8)	0.6 (0.2 to 0.9)	<0.0001
8-12 years:		n=102			n=83			
Psychosomatic wellbeing	31.5 (7.9)	34.7 (6.0)	3.2 (1.9 to 4.5)	31.2 (6.1)	33.8 (7.0)	2.6 (1.4 to 3.8)	0.6 (–1.2 to 2.4)	0.360
Effects on social life	25.8 (4.2)	27.0 (3.8)	1.1 (0.4 to 1.8)	26.3 (4.0)	27.2 (3.5)	0.9 (0.2 to 1.6)	0.2 (–0.8 to 1.2)	0.940
Confidence in medical treatment	17.0 (4.0)	20.1 (3.2)	3.1 (2.2 to 3.9)	17.4 (3.9)	17.5 (4.4)	0.1 (–0.7 to 1.0)	2.9 (1.7 to 4.1)	<0.0001
Emotional coping	13.7 (3.3)	16.4 (2.8)	2.7 (2.0 to 3.4)	14.7 (3.2)	15.6 (3.4)	0.9 (0.2 to 1.6)	1.8 (0.9 to 2.8)	0.002
Acceptance of disease	7.3 (1.9)	8.1 (1.5)	0.8 (0.4 to 1.2)	7.4 (1.7)	7.7 (1.8)	0.2 (–0.2 to 0.6)	0.6 (0 to 1.2)	0.031

groups were highly motivated and tried to optimise their therapies. Any treatment interventions were not restricted in either intervention or control groups. We monitored treatments by questionnaire and found no major imbalances between study arms. The effect of education on long term improvements of disease severity was noticeable and compares favourably with the improvement in disease management achievable by drug intervention alone.

It is well known that patients with an identical composite score on the scoring of atopic dermatitis scale may differ greatly in the measures of individual items. To our knowledge, however, even a 5 point improvement in the score might be clinically relevant for an individual patient.

The design of the programme, developed by the German atopic dermatitis intervention study, differs from previous psychosocial interventions. The educational programme comprises a 40 hour training workshop for teachers qualified in atopic dermatitis. The programme is offered by institutions with national certification for the education of children and adolescents with the disease. A facility that provides education in atopic dermatitis must have at least one certified trainer, as well as further team members, for the programme to be correctly administered by doctors and psychologists, in combination with nutritionists or dietitians. One new and notable aspect of the educational programme is the promotion of cooperation between different professionals, despite the highly diverse approaches of the different disciplines.

In Germany, although almost all established inpatient departments specialising in atopic dermatitis offer patient education, the ideal situation is one in which educational facilities are associated with a college that has long term experience in patient education and is able to offer supervision and instructed seminars (so called "train the trainer" workshops). In 2000 the Association for Atopic Eczema Education established eight colleges in Germany to fulfil these needs.

Our study expands on the positive results seen with adult educational programmes[17–19] and shows that such an approach works well in the control of atopic dermatitis in children and adolescents. Our results support those observed in previous single centre studies with smaller numbers of patients, which showed a beneficial effect of education in children with atopic dermatitis and their parents.[7 20] In particular, Staab et al showed that parents' quality of life improved significantly in the intervention groups compared with a control group, using a programme that provided the basis for the intervention presented here.[21]

A strategy that maximises patient and parent education can complement a symptom oriented therapeutic approach.[22] Such an approach is appropriate for atopic dermatitis, when psychological and nutritional factors and a combination of topical and systemic therapies may need to be considered to tackle the underlying multifactorial pathophysiology of this chronic disease.[23] In addition to treating the symptoms of atopic dermatitis in childhood and adolescence, giving parents educational support is an important factor in achieving a positive long term outcome.[12]

Although the value of programmes for the prevention of atopic dermatitis is recognised, this approach is usually used when basic therapy and expert medical attention have failed, and is not used as a primary means of disease management. We included in our study only families of children diagnosed as having moderate to severe atopic dermatitis (>20 on scoring of atopic dermatitis scale). However a study that evaluated educating adult patients about atopic dermatitis showed that those patients with less severe symptoms derived greater benefit.[24] Future studies should tackle the target groups that would benefit most from education.

In conclusion we found that age related educational programmes for the control of atopic dermatitis in children and adolescents are significantly more effective in the long term management of the disease than is conventional treatment. Such programmes should be considered for integration into routine care.

What is already known on this topic

Atopic dermatitis is a chronic skin disease with a high prevalence and high burden

Lack of information and lack of confidence in medical treatment lead to suboptimal management of the disease

What this study adds

Age related educational programmes improve the long term management of atopic dermatitis

Both parents of affected young children and adolescents reported reduced severity of eczema and improved quality of life

Contributors: DS was study coordinator. She was responsible for the educational programme in one of the study centres and was involved in the study design, evaluation of the instruments, and development of the programme. TLD was responsible for the evaluation centre and data management, was involved in the study design, evaluation of the instruments, and the development of the medical content of the programme, and wrote the paper with UG and DS. MF was responsible for one of the study centres and was involved in the development of the medical content of the programme. JK was involved in the development and testing of the evaluation instruments. TL-C was involved in the development of the child educational part of the programme. JR was responsible for one of the study centres and was involved in the development of the medical content of the programme. SS was responsible for the inpatient study centre and was mainly involved in the development of the adolescent part of the programme and didactic topics. RS was involved in the study design, data management, and evaluation. GS-O was involved in the development of the psychological content of the programme and in the evaluation. CS was responsible for the educational programme in one of the study centres and was involved in the development of the medical content of the programme. RSch was responsible for one of the study centres and was involved in the development of the medical content of the programme. TW was responsible for one of the study centres and was involved in the development of the medical content of the programme and the didactic presentation of the manuals. MW was responsible for the educational programme in one of the study centres and was involved in the didactic development of the programme. UW was principal investigator, initiated the proposal and was involved in the study design. UG was involved in the study design and was head of the evaluation group. All authors approved the final draft. DS, TLD, MF, JR, RSch, TW, and UG are guarantors.

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Department of Paediatric Pulmonology and Immunology, Charité, Humboldt University, Berlin
Doris Staab *paediatric allergologist*
Ulrich Wahn *professor*

Department of Clinical Social Medicine, Occupational and Environmental Dermatology, University Hospital Heidelberg, Thibautstrasse 3, D-69115 Heidelberg, Germany
Thomas L Diepgen *professor*
Reginald Scheidt *epidemiologist*

Department of Dermatology, University Erlangen, Germany
Manig Fartasch *professor*

Department for Medical Psychology, Justus-Liebig-University Giessen, Germany
Jörg Kupfer *psychologis*

Childrens Hospital Osnabrück, Germany
Thomas Lob-Corzilius *paediatric allergologist*
Rüdiger Szczepanski *paediatric allergologist*

Department of Dermatology and Allergy Biederstein, Technical University Munich, Germany
Johannes Ring *professor*
Christina Schnopp *dermatologist*

Rehabilitation Clinic for Children and Adolescents, Sylt, Germany
Sibylle Scheewe *paediatric allergologist*

Department of Psychosomatic Medicine, Hannover Medical School, Germany
Gerhard Schmid-Ott *professor*

Department of Dermatology and Allergology, Hannover Medical School, Germany
Thomas Werfel *professor*

Childrens' Hospital Amsterdamer Strasse, Köln, Germany
Marita Wittenmeier *atopic dermatitis trainer*

Department of Psychosomatic Medicine and Psychotherapy, Justus-Liebig-University Giessen, Germany
Uwe Gieler *professor*

Correspondence to: T L Diepgen thomas_diepgen@med.uni-heidelberg.de